



## Centers for Medicare & Medicaid Services

[Document Identifier: CMS-29, CMS-437, CMS-10185 and CMS-10452]

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.
2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number \_\_\_\_\_

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:**

*Contents*

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-29      Verification of Clinic Data - Rural Health Clinic Form and Supporting Regulations

CMS-437      Psychiatric Unit Criteria Work Sheet

CMS-10185   Medicare Part D Reporting Requirements

CMS-10452   CMS Identity Management (IDM) System

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of

information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

### *Information Collection*

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Verification of Clinic Data - Rural Health Clinic Form and Supporting Regulations; *Use:* The form is utilized as an application to be completed by suppliers of Rural Health Clinic (RHC) services requesting participation in the Medicare program. This form initiates the process of obtaining a decision as to whether the conditions for certification are met as a supplier of RHC services. It also promotes data reduction or introduction to and retrieval from the Automated Survey Process Environment (ASPEN) and related survey and certification databases by the CMS Regional Offices. Should any question arise regarding the structure of the organization, this information is readily available. *Form Number:* CMS-29 (OMB control number 0938-0074); *Frequency:* Occasionally (initially and then every six years); *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 1,887; *Total Annual Responses:* 5,661; *Total Annual Hours:* 1,269. (For policy questions regarding this collection contact Shonte Carter at 410-786-3532.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Psychiatric Unit Criteria Work Sheet; *Use:* Certain specialty hospitals and hospital specialty distinct-part units may be excluded from the Inpatient Medicare Prospective Payment System (IPPS) and be paid at a different rate. These specialty hospitals and distinct-part units of hospitals include Inpatient Rehabilitation Facilities (IRFs) units, Inpatient Rehabilitation Facilities (IRFs) hospitals and Inpatient Psychiatric Facilities (IPFs).

CMS regulations at 42 CFR 412.20 through 412.29 describe the criteria under which these specialty hospitals and specialty distinct-part hospital units are excluded from the IPPS. Form CMS-437 is used by Inpatient Psychiatric Facilities (IPFs) to attest to meeting the necessary requirements

that make them exempt for receiving payment from Medicare under the IPPS. These IPFs must use CMS-437 to attest that they meet the requirements for IPPS exempt status prior to being placed into excluded status. The IPFs must re-attest to meeting the exclusion criteria annually. *Form Number:* CMS-437 (OMB control number: 0938-0358); *Frequency:* Annually; *Affected Public:* Private sector - Business or other for-profits; *Number of Respondents:* 1,598; *Total Annual Responses:* 1,598; *Total Annual Hours:* 1,732. (For policy questions regarding this collection contact Caroline Gallaher at 410-786-8705.)

3. *Type of Information Collection Request:* Revision of a previously approved collection; *Title of Information Collection:* Medicare Part D Reporting Requirements; *Use:* Section 1860D-12(b)(3)(D) of the Act provides broad authority for the Secretary to add terms to the contracts with Part D sponsors, including terms that require the sponsor to provide the Secretary with information as the Secretary may find necessary and appropriate. Pursuant to our statutory authority, we codified these information collection requirements for Part D sponsors in regulation at 42 CFR §423.514(a).

Data collected via the Medicare Part D reporting requirements will be an integral resource for oversight, monitoring, compliance, and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. For all reporting sections (Enrollment and Disenrollment, Medication Therapy Management (MTM) Programs, Grievances, Improving Drug Utilization Review Controls, Coverage Determinations and Redeterminations, and Employer/Union Sponsored Sponsors), data are reported electronically to CMS. The data collected via the MTM and Grievances reporting sections are used in the Medicare Part C and D Star Ratings and Display Measures. The other reporting sections' data are analyzed for program oversight to ensure the availability, accessibility, and acceptability of sponsors' services, such as coverage determinations and appeals processes, and opioid safety edits at the time of dispensing. *Form Number:* CMS-10185 (OMB control number: 0938-0992); *Frequency:* Yearly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 814; *Total Annual Responses:* 12,575; *Total Annual Hours:* 16,463. (For policy questions regarding this collection contact Chanelle Jones at 410-786-8008).

4. *Type of Information Collection Request:* Extension of a previously approved collection; *Title of Information Collection:* CMS Identity Management (IDM) System; *Use:* HIPAA regulations require covered entities to verify the identity of the person requesting Personal Health Information (PHI) and the person's authority to have access to that information. Per the HIPAA Security Rule, covered entities, regardless of their size, are required under Section 164.312(a)(2)(i) to "assign a unique name and/or number for identifying and tracking user identity." A 'user' is defined in Section 164.304 as a "person or entity with authorized access". Accordingly, the Security Rule requires covered entities to assign a unique name and/or number to each employee or workforce member who uses a system that receives, maintains or transmits electronic PHI, so that system access and activity can be identified and tracked by user. This pertains to workforce members within health plans, group health plans, small or large provider offices, clearinghouses and beneficiaries.

The information collected will be gathered and used solely by CMS, approved contractor(s), and state health insurance exchanges to prove the identity of an individual requesting electronic access to CMS protected information or services. Information confidentiality will conform to the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the Federal Information Security Management Act (FISMA) requirements. Respondents may also access CMS' Terms of Service and Privacy Statement on the CMS Portal and IDM websites.

CMS has moved from this centralized on premise model for enterprise identity management to a cloud-based solution, IDM, with multiple products providing specialized services: Okta Identity as a Service (IDaaS), which includes Multi-Factor Authentication (MFA) services; Experian Remote Identity Proofing (RIDP) services; and Cloud Computing Services-Amazon Web Services/Information Technology Operations (CCS-AWS/ITOps) Hub Hosting. In order to prove the identity of an individual requesting electronic access to CMS protected information or services, IDM (leveraging Experian Precise ID RIDP services) will collect a core set of attributes about that individual. *Form Number:* CMS-10452 (OMB control number: 0938-1236); *Frequency:* Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 560,000; *Total Annual*

*Responses: 560,000; Total Annual Hours: 186,667. (For policy questions regarding this collection contact Malachi Robinson at 410-786-1849).*

Dated: March 16, 2021.

**William N. Parham, III,**

*Director,*

*Paperwork Reduction Staff,*

*Office of Strategic Operations and Regulatory Affairs.*

**4120-01-U-P**

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